

REMARKS

Claims 1 and 3 are currently amended, and claims 35 and 45 have been cancelled without prejudice to Applicant's rights to file one or more continuation or divisional applications for the subject matter of those claims. Claims 1-20, 34, 36-44 and 46-47 appear in the application for the Examiner's consideration. The amendments to claims 1 and 3 are supported by the original claims and specification, for example page 5 lines 9 and 20-24, page 17 line 9 and original claims 1, 3, 13, 14 and 21. No new matter has been added. As no new matter has been introduced, Applicant respectfully requests that the amendments and the new claims be entered at this time.

Claim 1 is rejected under 35 U.S.C. §112, first paragraph, as based on a disclosure which is not enabling. Specifically, the Examiner states that claim 1, as amended, does not provide a detail description of the residues that would be included by the proviso "other than Gly". The Examiner asserts that the only specific description for the other residue is lysine (Lys). However, the proviso encompasses all natural, unnatural, charge or uncharged amino acid other than Gly. The Examiner asserts that the single residue described in the specification is therefore insufficient support for the proviso, as recited.

Applicant respectfully requests reconsideration of these statements. Applicant has now amended Claim 1 to incorporate the features of previous claim 45 and recite a charged residue at position 44. Claim 45 has concurrently been cancelled. Applicant submits that, because lysine is a charged residue, the specification sufficiently supports amended claim 1, which now recites exactly what is present at position 44.

In view of the foregoing, Applicant respectfully requests that this rejection be withdrawn.

The Examiner states that claim 34, as amended, reciting a polypeptide that is predominantly monomeric, is not supported in the as-filed specification. The Examiner asserts that the specification does not provide a definition, percent or amount of the monomer of a polypeptide that is considered predominant in a sequence.

Applicant respectfully requests reconsideration of this statement. Applicant respectfully submits that the term "predominantly" is explicitly supported by the specification as filed. Specifically, page 13 lines 1-6 read as follows:

“Biophysical analysis of the VH protein using analytical ultracentrifugation revealed that the VH could be maintained predominantly as a monomer. Although it has a very weak tendency to dimerize, with a dissociation

equilibrium constant for dimer formation of 1.1 mM, no indications of higher oligomers were found. This suggests that high concentrations of VH protein can be achieved without stability problems that occur due to aggregation. This is the first demonstration of such analysis on VH protein”.

The specification clearly recites a quantitative value of the monomer which could easily be understood by a person skilled in the art.

In view of the foregoing, Applicant respectfully requests that this rejection be withdrawn.

Claims 1-4, 9-10, 19, 34-36, 40 and 45-47 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The Examiner states that Applicant's remarks as to the Figure 1 and Seq. ID. No. 2 reciting Lys at the 45th position is unclear. The Examiner states that even in the presence of a 35a residue as shown in the Reiter article, still residue 44 will be considered the 44 position with said lysine. Applicant respectfully requests reconsideration of this statement. Applicant submits that since the sequence listing cannot and does not include 35a, said modified residue numbered 44 in the specification is at position 45 in the sequence listing and in figure 1.

B. The Examiner states that claims 3 and 35 are confusing and broaden the base claim 1 with the recitation of different and various compounds such as polynucleotide, vectors, phage display library etc. Applicant respectfully requests reconsideration of this statement. Applicant has now amended claim 3 to remove reference to an expression vector. Applicant has also now cancelled claim 35. Claim 3 merely recites various limitations pertaining to the polynucleotide encoding the claimed polypeptide, and therefore complies with the requirements under 35 U.S.C. §112, second paragraph.

C. The Examiner states that claims 4 and 36 are indefinite as they relate to a method step and broaden the base claim with the recited *E. Coli*. The Examiner states that Applicant's previous arguments and amendments to claims 4 and 36 - namely that claims 4 and 36 further define the polypeptide of claims 3 and 35, render these claims more confusing. Applicant respectfully requests reconsideration of this statement. Applicant respectfully submits that it is possible to produce the polypeptides in other hosts such as unicellular organisms, whether prokaryotic or eukaryotic, or cell lines from multicellular organisms, whether plant or animal, the latter ranging from insect to mammalian cells (see

page 4 line 24 - page 5 line 2). Therefore restricting production to one host merely limits the scope of the claim to one embodiment and is not confusing.

D. The Examiner states that claims 10 and 40, reciting the sequence between residues 95 and 100C, are confusing as to the recited 95 and 100C. The Examiner states that Applicant's response with regards to the Kabat nomenclature is not acceptable, since there is nothing in the specification that alludes to the Kabat nomenclature. Applicant respectfully requests reconsideration of this statement. Applicant submits that the Kabat nomenclature is clearly mentioned in the specification on page 11 lines 17-19, page 16 lines 16-17 and page 17 lines 10-11 and that in any event skilled artisans fully understand this nomenclature.

E. The Examiner states that the term "predominantly" lacks support in the specification, and is therefore indefinite. Applicant respectfully requests reconsideration of this statement. The term "predominantly" is recited in the Specification on page 13 line 2, as detailed hereinabove on pages 6 and 7 of this Amendment.

F. The Examiner states that claims 19 and 35 are identical as they contain the same limitations. In response, Applicant has now cancelled claim 35 to avoid duplication.

G. The Examiner states that claim 47 is a duplicate of claim 19, as the same ingredients in each instance is being claimed. The Examiner states that the manner by which the polypeptide of claim 19 is obtained does not have a bearing on the composition that contains the polypeptide and carrier components. Applicant respectfully requests reconsideration of this statement. Applicant submits that claim 3 further defines the invention of claim 1 in with respect to the polynucleotide encoding the claimed polypeptide. It follows that claim 19, which is ultimately dependent on claim 3, is more specific in scope than claim 47, which ultimately depends on claim 1.

In view of the foregoing, Applicant respectfully requests that all rejections under 35 U.S.C. §112, second paragraph be withdrawn.

Claims 1-4, 9-10, 19, 34-36, 40 and 47 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The Examiner bases this rejection on an article written by Reiter et al (JMB 1999). The Examiner states that Applicant's arguments as to the priority date of the subject application are not acceptable, since the priority document submitted by Applicant is not presently on file.


Applicant respectfully requests reconsideration of this statement. Applicant has submitted the certified copy of the Israeli priority 127127, in a response dated October 21, 2003. As that application is in English, the priority date of November 11, 1998 has been

established for the claimed subject matter. In addition, the Examiner states that there is no evidence on the record, e.g. in the form of a declaration, that the other authors are not inventors. Even though this is true, Applicant submits that no such declaration is deemed necessary, since the Reiter publication was made after the priority date and is not an effective prior art reference. For these reasons, all rejections based on Reiter should be withdrawn and all current claims should be allowed.

In view of the above, the entire application is believed to be in condition for allowance, early notice of which would be appreciated. Should any issues remain, a personal or telephonic interview is respectfully requested to discuss the same in order to expedite the allowance of all the claims in this application.

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Respectfully submitted,


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